introduction, and delivery for introduction, into interstate commerce of large quantities of said devices known as rubber *prophylactics;* that the said devices manufactured, purchased, packed, distributed, and sold by the defendants were recommended and purported to be sold for the prevention of venereal diseases; and that the devices were adulterated and misbranded in the following respects: Adulteration, Section 501 (c), the devices consisted of defective, imperfect, and old materials, and contained holes, defects, and other imperfections, so that their strength differed from, and their quality fell below, that which they purported and were represented to possess; and, misbranding, Section 502 (a), the statements in the labeling "Perfection Supreme Quality Prophylactics" were false and misleading.

The complaint alleged further that the defendants had shipped large quantities of devices in interstate commerce; that many of the shipments had been examined, found defective, and seized; that the methods of manufacture were primitive and inefficient; that the resulting product would be ineffective to prevent disease; that the defendants had in their possession a large supply of defective prophylactics which were adulterated and misbranded as aforesaid and which they intended to introduce, and were introducing, into interstate commerce; and that unless restrained and enjoined, they would continue such introduction and delivery into interstate commerce.

PRAYER OF COMPLAINT: That a temporary restraining order be granted, followed by a preliminary injunction enjoining the defendants from the commission of the acts complained of, and that upon final hearing the preliminary injunction be made permanent.

DISPOSITION: On November 27, 1945, a preliminary injunction was entered enjoining the defendants during the pendency of the action from commission of the acts complained of. On September 4, 1947, the defendants having admitted the allegations of the complaint and consented to the entry of a decree, the court entered a decree making the preliminary injunction permanent.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2375. Alleged misbranding of Alberty's products. U. S. v. Ada J. Alberty (Alberty Food Products). Defendant's demurrer to information overruled. Plea of not guilty. Tried to the court. Judgment of guilty by district court, with probation for 3 years. Judgment reversed by Circuit Court of Appeals for Ninth Circuit. (F. D. C. No. 16522. Sample No. 81338–F, et al.)

INFORMATION FILED: On or about December 5, 1945, Southern District of California, against Ada J. Alberty, trading as Alberty Food Products, Hollywood, Calif. The information included 14 shipments of 14 different products of the defendant. All counts of the information were dismissed, with the exception of count 23 involving *Alberty Calcium Pantothenate Tablets.*

ALLEGED SHIPMENT: The products were shipped between the approximate dates of October 18, 1943, and April 18, 1944, from the State of California into the State of Missouri. Certain printed matter which related to the article, and which had been shipped to the consignee on or about February 7, 1944, was alleged to constitute accompanying labeling. The *Alberty Calcium Pantothenate Tablets* were shipped on or about April 18, 1944.

LABEL, IN PART: (*Alberty Calcium Pantothenate Tablets*, bottle label) "100 Tablets 10 Mg. (10,000 Micrograms) each of Calcium Pantothenate per tablet. Contains Dextrorotatory, Calcium Pantothenate, Dextrose and Vegetable Stearin."

NATURE OF CHARGE: *Alberty Calcium Pantothenate Tablets.* Misbranding, Section 502 (a), certain statements in leaflets entitled "So it's You again, is it?" shipped on or about February 7, 1944, were alleged to be false and misleading, in that they represented and suggested that the article would be efficacious to restore color to gray hair and to prevent hair from turning gray, whereas the article would not be efficacious for such purposes.

The information alleged also that the other products shipped by the defendant, as stated above, were misbranded because of false and misleading statements contained in the literature shipped on February 7, 1944, and that in some instances they were misbranded further with respect to their labels.

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*See also Nos. 2352, 2354, 2358–2362, 2365, 2366, 2372, 2374.

DISPOSITION: On or about January 21, 1946, the defendant entered a plea of not guilty and filed a demurrer to the information. The court overruled the demurrer on February 11, 1946. Thereafter, the case proceeded to trial before the court on an agreed stipulation of facts covering count 23, relating to the *Alberty Calcium Pantothenate Tablets*, and on or about May 20, 1946, the court handed down the following opinion:

HARRISON, *District Judge*: "This is a criminal case wherein the defendant is charged in twenty-three (23) counts with a violation of the Federal Food, Drug and Cosmetic Act (Title 21, U. S. C., Sec. 301 et seq.). All counts, with the exception of Count XXIII, have been dismissed, and the case has been submitted to me on an agreed stipulation of facts, jury trial having been waived by both parties.

"All the allegations of Count XXIII are admitted, except that the defendant denies the offending circular accompanied the drug in interstate commerce within the definition of 'labeling' under the provisions of 21 U. S. C. A., Sec. 321 (m):

> Sec. 321 (m)—The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

"The stipulation of facts discloses that the leaflets were shipped on February 7, 1944, while the drugs were not shipped until April 25, 1944. Thus there was a lapse of seventy-one (71) days between the shipping of the offending circulars and the drug. Both were shipped in interstate commerce, had a common destination, and were displayed together.

"Thus the sole issue is whether the drug and leaflets accompanied each other within the purview of the Act. Stating the issue differently, can the salutary objectives of the Act be circumvented by permitting a lapse of time to exist between the shipment of the drugs and offending leaflets from a common source to a common destination? I think not.

"I have been able to find but three cases that may be deemed as precedents. The first case is one from our own circuit, to-wit:—UNITED STATES v. RESEARCH LABORATORIES, IND., 126 F (2) 42, 45, wherein the Court stated:

> The libel does not state, nor is it material, whether the packages and circulars did or did not travel in the same crate, carton or other container, or on the same train, truck or other vehicle during their interstate journey. The packages and the circulars had a common origin and a common destination and arrived at their destination simultaneously. Clearly, therefore, they accompanied each other, regardless of whether, physically, they were together or apart during their journey.

"The defendant feels that this case supports her position because of the simultaneous arrival of the offending articles. The facts in UNITED STATES v. RESEARCH LABORATORIES, IND., supra, indicated a simultaneous arrival and that was as far as the Court was called upon to go. The Court's attitude towards a liberal interpretation of this Act is clearly brought out, when the Court further stated:

> The rule of strict construction invoked by appellee has little or no application to statutes designed, as the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A., Sec. 301 et seq., is designed, to prevent injury to the public health. A. O. ANDERSON & CO. v. UNITED STATES, 9 Cir. 284 Fed. 542, 543; UNITED STATES v. 48 DOZEN PACKAGES OF GAUZE, 2 Cir. 94 Fed. 2d., 641, 642.

"The second case that conforms to my conclusions is UNITED STATES v. LEE, 131 F. (2) 464. As in the case at bar, the circulars were shipped in interstate commerce separately from the products to which they relate. Therein the Court held as follows:

> The word "accompany" is not defined in the Act, but we observe that among the meanings attributed to the word are "to go along with," "to go with or attend as a companion or associate," and "to occur in association with," Webster's New International Dictionary, 2d. Ed. There can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates, and that the basic character of the Federal Food, Drug, and Cosmetic Act is not directly concerned with the sale of the products therein described, or whether the literature is carried away by the purchaser. It was enacted to protect the public health and to prevent fraud, and it ought to be given a liberal construction. Consequently, we are impelled to the conclusion that misbranding is cognizable under the Act if it occurs while the articles are being held for sale.

"The third case is UNITED STATES v. 7 JUGS etc., 53 Fed. Sup. 746, wherein an attempt was made to circumvent the Act by permitting a lapse of

time to occur between the shipment of the related articles. The Court disposed of this issue in the following language:

> The physical aspects of the transportation are not important. What is vital here are such factors as interdependence of the drug and the booklets, common origin, common destination, display, distribution and use together. These determine whether there has been that degree of accompaniment which provides the necessary "misbranded" status under Section 304 (a). The mere fortuitous circumstance of an absence of physical association between the booklets and drugs during the interstate journey of the drugs does not in my opinion control.

"Besides the foregoing formidable authorities, common sense and reason dictates the same conclusion. The Act was primarily promulgated to protect the consuming public. (UNITED STATES v. TWO BAGS, etc., 147 F. (2) 123–127.) If that is true, what difference does it make in what manner the circular and drug made their interstate journey, so long as they eventually came together upon the merchant's shelf, there to mislead and defraud the consuming public? When the drug and related circular came together, the prohibited act occurred, irrespective of the circuitous route each may have traveled.

"The Act involved has with unanimity been liberally construed to protect the consuming public from the avaricious. U. S. v. 95 Barrels of Vinegar, 265 U. S. 438, 44 S. Ct. 529, 68 L. Ed. 1094; U. S. v. Antikamnia Chemical Co., 231 U. S. 654, 655, 34 S. Ct. 222, 58 L. Ed. 419; U. S. v. Schider, 246 U. S. 519, 522, 38 S. Ct. 369, 62 L. Ed. 863; A. O. Anderson and Co. v. U. S., 284 Fed. 542; C. C. Co. v. U. S., 147 Fed. (2) 820; U. S. v. Commercial Creamery Co., 43 Fed. Sup. 714.

"The defendant relies solely upon a strict interpretation of the statute invoking the principle set forth in the dissenting opinion of Mr. Justice Murphy in UNITED STATES v. DOTTERWEICH, 320 U. S. 277, and again in the recent opinion of the Supreme Court in M. KRAUSE & BROS. v. UNITED STATES, decided on March 25, 1946.

"The cases heretofore cited clearly indicate that our courts have not applied the usual rule of strict construction of criminal statutes to this Act, but have given it a liberal construction and thus enabled the Act to accomplish its remedial purpose of protecting public health and pocket book against misbranded foods and drugs.

> Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government, and not merely as a collection of English words. * * * But that is not the way to read legislation. Literalism and evisceration are equally to be avoided. [Mr. Justice Frankfurter in U. S. v. Dotterweich, 320 U. S. 277.]
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> All construction is the ascertainment of meaning. And literalism may strangle meaning. [Mr. Justice Frankfurter in Utah Junk Co. v. Paul A. Porter, etc., U. S., decided April 22, 1946.]

"If this Act is to be treated as a working instrument and not merely as a collection of English words, it must be interpreted as a living and vitalized Act. The defendant seeks, through literalism and evisceration, to avoid her studied attempt to circumvent the Act.

"I hold that the word 'accompany' as used in the Act means that when a drug and a related circular, having a common source and a common destination, come together at their destination, they are united and become one in so far as the buying public is concerned, each, in effect, accompanying the other, whether they arrived at their common destination simultaneously or otherwise.

"In view of my conclusions herein expressed, it is my opinion the drug described in Count XXIII was misbranded contrary to the provisions of the Federal Food, Drug and Cosmetic Act, and therefore the defendant is guilty as charged."

In accordance with the foregoing opinion, the defendant was found guilty and was sentenced to 3 years' probation on or about May 20, 1946. An appeal was taken to the United States Circuit Court of Appeals for the Ninth Circuit, and on January 31, 1947, the following opinion was handed down by that court, reversing the judgment of the district court:

DENMAN, *Circuit Judge:* "Appellant appeals from a judgment sentencing her to three years on probation for violation of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. 331 (a).

"The language of the information is that—

> . . . Ada J. Alberty, . . . doing business . . . at Hollywood, Los Angeles, State of California, did . . . on or about April 18, 1944 *then and there,* in violation of the Act

of Congress . . . 21 U. S. C. 331 (a),[1] unlawfully introduce and deliver for introduction into interstate commerce, from Hollywood, Los Angeles, State of California, to Kansas City, State of Missouri, consigned to Natural Food Store, a certain consignment to wit, a number of bottles containing a drug within the meaning of 21 U. S. C. 321 (g) (2) . . .

That displayed upon written, printed, and graphic matter *accompanying said drug when introduced and delivered for introduction into interstate commerce,* as aforesaid, namely upon a number of leaflets entitled "So it's You again, is it?" relating to said drug which said leaflets were shipped by the said Ada J. Alberty trading and doing business as "Alberty Food Products" to said Natural Food Store *prior to the date of the shipment of said drug as aforesaid,* to wit, *on or about February 7, 1944,* were among other things the following statements: . . .

That said drug, when introduced and delivered for introduction into interstate commerce, as aforesaid, was *then and there* misbranded within the meaning of the said act of Congress [21 U. S. C. 352 (a)], in that the statements aforesaid appearing in the leaflets entitled "So it's You again, is it?" *accompanying* said drug, as aforesaid were false and misleading in this, that said statements represented and suggested that said drug would be efficacious to restore color to gray hair and would be efficacious to prevent hair from turning gray; whereas in fact and in truth said drug would not be efficacious to restore color to gray hair and would not be efficacious to prevent hair from turning gray. [Emphasis supplied.]

"Appellant demurred to the information on the ground that it does not charge an offense within the sections of the Federal Food, Drug, and Cosmetic Act, contending to the court below, as follows:

The Act in question (Secs. 343–a and 352–a of Title 21, U. S. C.) provides that a food or drug shall be deemed to be misbranded "if its labeling is false or misleading in any particular." Another section of the Act (Sec. 321–m of Title 21, U. S. C.) defines the term "labeling" to mean "all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers or (2) accompanying such article." . . .

and that the labels did not accompany the drug within Section 321 (m).

"The district court overruled the demurrer, thus ruling against appellant's contention that the literature did not accompany the drug when it was introduced into interstate commerce. Appellant assigns this ruling as error.

"Section 331 (a) provides

Prohibited acts

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded. [Emphasis supplied.]

"It will be noted that the verb 'is' is in the present tense. Section 331 (a) confines the offense to a misbranding at the 'introduction or delivery for introduction into interstate commerce' as recognized in the information by the use of the words 'then and there.'

"A drug is misbranded 'If its labeling is false or misleading in any particular.' 21 U. S. C. 352 (a). 'Labeling' of an article is defined to mean 'all labels * * * accompanying such article.' 21 U. S. C. 321 (m).

"The information charges that the false labels were shipped by appellant to the Natural Food Store at Kansas City, Missouri, on February 7, 1944, that is two months and eleven days before April 18, 1944, when the drug was 'then and there' introduced into interstate commerce. It does not allege that the labels were to be placed with the drug or used together with it by the consignee. For all the information alleges, the labels may not have arrived in Missouri. Or they may have been destroyed. Or they may have been distributed to the prospective customers a month before the arrival of the drug in Missouri and hence never accompanied it there. Or they may have been used in connection with other drugs shipped and sold long prior to April 18, 1944, when the charged offense is alleged 'then and there' to have been committed.

"We do not think that the bald statement that the labels were shipped to the Missouri consignee seventy-one days before the drug was shipped charges the offense of causing them to be 'accompanying' the drug's introduction into interstate commerce on or about April 18, 1944.

"Appellee cites our decision United States v. Research Laboratories, Inc., (CCA 9), 126 F. 2d 42. In that case, a condemnation proceeding, the libel

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[1] There is another provision of the Act, 21 U. S. C. 331 (k), forbidding misbranding after the drug has passed through interstate commerce, as follows:

"(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."

This section has no application to a charge that at the moment of introducing the drug into interstate commerce the misbranding "then and there" occurred.

charged that the false circulars accompanied the drug into interstate commerce and all arrived at their common destination simultaneously. The information in the instant appeal alleges no such facts and, on the contrary, cannot be construed as charging that the drug and labels were in interstate commerce at the same time, much less introduced therein at the same time. United States v. 7 Jugs of Dr. Salsbury's Rakos, 53 F. Supp. 746, has similar facts and follows the Research Laboratories case.

"Appellee also cites United States v. Lee, (CCA-7), 131 F. 2d 464. The complaint there sought an injunction because of an entirely different offense—the placing of the drug and false printed matter together *after* the interstate shipment in violation of 331 (k), referred to in our footnote above. It in no way supports the information purported to be based upon the claimed violation of 321 (m) at the time of shipment, to which appellant demurred.

"These three cases were civil proceedings and not criminal prosecutions. They construe the Act liberally. The question was raised at the hearing here whether in construing the Act as the basis of a criminal prosecution there should be a similar construction against the accused. Cf. the recent case of Kraus & Bros., Inc. v. United States, 327 U. S. 614, 621, construing in a criminal proceeding the Emergency Price Control Act which, like the Food, Drug, and Cosmetic Act, also afforded civil relief. There the Supreme Court states

> This delegation to the Price Administrator of the power to provide in detail against circumvention and evasion, as to which Congress has imposed criminal sanctions, creates a grave responsibility. In a very literal sense the liberties and fortunes of others may depend upon his definitions and specifications regarding evasion. Hence to these provisions must be applied the same strict rule of construction that is applied to statutes defining criminal action * * *

"However, we think that, whatever the criterion of construction, the ordinary use of the word 'accompanying' which we have here accepted is that applicable.

"After overruling the demurrer, the case was tried on a stipulation of facts which stated that the shipment of labels was received by the consignee on February 11, 1944, and the drug on April 25, 1944, clearly establishing that the two did not accompany each other when introduced into interstate commerce nor at any time in that interstate transit. It was also stipulated that they were exhibited together in the consignee's store. Here there might be said to be accompaniment *after* the interstate commerce was completed, but nothing is stipulated as to appellant's then ownership or control of the drug and labels or her participancy in these later acts to bring her within 331 (k), a section not involved in the information.

"The judgment is reversed, the case is remanded, and the information ordered to be dismissed."

2376. Misbranding of solution of magnesia sulfate with citrate of magnesia. U. S. v. Roma Extract Co., Vincenzo Contrino, and Joseph Graceffa. Pleas of guilty. Fine of $50 against each defendant. (F. D. C. No. 23581. Sample Nos. 57179-H, 57635-H.)

INFORMATION FILED: May 5, 1948, District of Massachusetts, against the Roma Extract Co., a partnership, Boston, Mass., and Vincenzo Contrino and Joseph Graceffa, partners.

ALLEGED SHIPMENT: On or about June 13 and December 30, 1946, from the State of Massachusetts into the State of Rhode Island.

NATURE OF CHARGE: Misbranding, Section 502 (a), the words "Citrate Magnesia" molded into the bottles of the article and "Citrate of Magnesia" appearing on the shipping cartons were false and misleading, in that such words represented and suggested that the article consisted of solution of magnesium citrate, commonly known as citrate of magnesia, whereas the article was essentially a solution of epsom salt; Section 502 (i) (1), the container of the article was so made and formed as to be misleading, in that the container resembled the bottle commonly used as a container for citrate of magnesia and bore the words "Citrate Magnesia" molded into the glass; and, Section 502 (i) (2), the article was an imitation of another drug, "Solution of Magnesium Citrate," commonly known to the trade and the public as citrate of magnesia.

DISPOSITION: June 8, 1948. Pleas of guilty have been entered, the court imposed a fine of $50 against each defendant.